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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,727

Applicant(s)

BROWN ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 14-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 33-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-13 and 33-43 in the paper filed March 29, 2004, is acknowledged. The traversal is on the ground(s) that claim 14 is supposed to be a linking claim and should be examined with the Group I claims. This is not found persuasive because claim 14 is not a linking claim. Claim 14, and the dependent claims, are drawn to an apparatus. As noted in the restriction, the apparatus can be used for many methods other than those of Group I. So the inventions are distinct. The burden is also expressly discussed in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. There are references provided, but no Information Disclosure Statement was found in the application.

Claim Objections

3. Claims 34-43 are objected to because of the following informalities: The claims depend from a withdrawn claim and claim 34 does not include all of the limitations within the elected claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112 – Written Description

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 34-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of "means plus function" claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, "means plus function" claims invoke 35 U.S.C. 112, sixth paragraph and represent a situation in which the specification defines the terms. However, in the current case, a careful review of the specification, including the drawings and claims, failed to identify any structural elements which achieved the claimed "means". Most significantly, no "means for removing the columns from the heads for disposal" was found in the specification. Therefore, the claims as written appear to lack a sufficient written description of the claims.

Similarly, there is no specific description of structures which meet the structural limitations of a "means for moving the head arrangement relatively downwardly" or "means for moving the head arrangement relatively upwardly".

Finally, the only structure stated is the use of a "bioblock", but a google search of this term identified many different structures that share this name, so this cannot provide structure to the claim.

Claim Rejections - 35 USC § 112 – Second Paragraph

6. Claims 34-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 34-43 depend from claim 26, which states “means (e.g. for providing pressure variation in the columns) for causing liquid samples ...” The use of the “e.g.” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

8. Further, claims 34-43 are indefinite because, as MPEP 2181 notes “If there is no disclosure of structure, material or acts for performing the recited function, the claim fails to satisfy the requirements of 35 U.S.C. 112, second paragraph.” As noted in the written description rejection above, there is no disclosure of structures necessary to meet several of the “means plus function” claim limitations.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

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Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1-10, 12 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Colpan et al (U.S. Patent 5,990,301).

Colpan teaches a method of obtaining a sample of a biomolecule from a suspension comprising a solution containing the biomolecule and insoluble material (see abstract and column 9, example 5), the method comprising the steps of:

(a) providing a biomolecule purification assembly comprised of a vessel having a liquid inlet and of a filter unit removably located on the liquid inlet (see column 9, example 5, where a filtration device is attached to a pressure device),

(b) effecting a filtration of the suspension through the filter unit so as to cause the solution to enter the vessel through the liquid inlet (see column 9, example 5, lines 60-65);

(c) removing the filter unit from the liquid inlet (see column 9, example 5, lines 66-67, where the filtration device is removed),

(d) immobilising the biomolecule on a solid phase support (see column 10, example 5, lines 5-6, where the DNA is immobilized on an anion exchange column); and

subjecting the biomolecule to at least one of the steps of washing on the support (see column 10, lines 7-8, where the column is washed) and elution from the support to

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obtain a purified sample of the biomolecule (see column 10, lines 9-10, where the biomolecule is eluted).

With regard to claims 2-4, Colpan teaches purification of plasmid DNA (see columns 9 and 10, example 5).

With regard to claim 5, Colpan teaches washing the solid phase support inside of a vessel, specifically a column (see column 10, lines 5-6).

With regard to claim 6, Colpan teaches elution by addition of elution solution through the column (see example 5).

With regard to claim 7, Colpan teaches that the suspension is prepared in a separate container which inherently has a well (see example 5).

With regard to claim 8, Colpan teaches the presence of NaCl which represents a binding agent (see example 5).

With regard to claim 9, Colpan teaches elution into a vessel (see column 10, example 5).

With regard to claim 10, Colpan teaches that the eluted material may be reassociated with affinity chromatographic supports after elution (see column 11, step d of claim 1).

With regard to claim 12, Colpan teaches the use of vertical columns (see example 5).

With regard to claim 33, Colpan teaches the steps of:

(i) providing a resuspension of bacterial pellet in solution (see column 9, lines 55-56),

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(ii) adding a lysis solution (see column 9, lines 57-59),

(iii) adding a neutralizing solution (see column 9, lines 60-62),

where the solutions are added to the solution without mechanical stirring (see column 9, lines 5-65, where the stirring is not mechanical).

11. Claims 1-10, 12 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Colpan et al (WO 95/21177).

Colpan teaches a method of obtaining a sample of a biomolecule from a suspension comprising a solution containing the biomolecule and insoluble material (see abstract and pages 19-20, example 5), the method comprising the steps of:

(a) providing a biomolecule purification assembly comprised of a vessel having a liquid inlet and of a filter unit removably located on the liquid inlet (see page 20, example 5, where a filtration device is attached to a pressure device),

(b) effecting a filtration of the suspension through the filter unit so as to cause the solution to enter the vessel through the liquid inlet (see example 5, page 20);

(c) removing the filter unit from the liquid inlet (see example 5, page 20, where the filtration device is removed),

(d) immobilising the biomolecule on a solid phase support (see example 5, page 20, where the DNA is immobilized on an anion exchange column); and

subjecting the biomolecule to at least one of the steps of washing on the support (see example 5, page 20, where the column is washed) and elution from the support to obtain a purified sample of the biomolecule (see example 5, page 20, where the biomolecule is eluted).

With regard to claims 2-4, Colpan teaches purification of plasmid DNA (see example 5, page 20).

With regard to claim 5, Colpan teaches washing the solid phase support inside of a vessel, specifically a column (see example 5, page 20).

With regard to claim 6, Colpan teaches elution by addition of elution solution through the column (see example 5, page 20).

With regard to claim 7, Colpan teaches that the suspension is prepared in a separate container which inherently has a well (see example 5, page 20).

With regard to claim 8, Colpan teaches the presence of NaCl which represents a binding agent (see example 5, page 20).

With regard to claim 9, Colpan teaches elution into a vessel (see example 5, page 20).

With regard to claim 10, Colpan teaches that the eluted material may be reassociated with affinity chromatographic supports after elution (see page 22, final step of claim 1).

With regard to claim 12, Colpan teaches the use of vertical columns (see example 5).

With regard to claim 33, Colpan teaches the steps of:

- (i) providing a resuspension of bacterial pellet in solution (see example 5, pages 19 and 20),
- (ii) adding a lysis solution (see example 5, pages 19 and 20),
- (iii) adding a neutralizing solution (see example 5, pages 19 and 20),

where the solutions are added to the solution without mechanical stirring (see example 5, pages 19 and 20, where the stirring is not mechanical).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Colpan et al (U.S. Patent 5,990,301) or Colpan et al (WO 95/21177); in view of Hawkins (U.S. Patent 5,705,628).

Colpan et al (U.S. Patent 5,990,301) or Colpan et al (WO 95/21177) each teach the limitations of claims 1-10, 12 and 33 as discussed above. Neither Colpan et al (U.S. Patent 5,990,301) nor Colpan et al (WO 95/21177) teach the use of magnetic beads for capture.

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Hawkins teaches capture of DNA on magnetic particles (see abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the magnetic beads of Hawkins in the method of Colpan et al (U.S. Patent 5,990,301) or Colpan et al (WO 95/21177) since Hawkins states "The present method simplifies the isolation of cloned DNA from lysate by obviating the need for centrifugation and produces a plasmid ready for sequencing and further characterization and processing. The present method also has the advantage that is fast, thus allowing for the rapid throughput in isolating polynucleotides, low cost and simple to perform and produces high yields of polynucleotides. These properties, coupled with its applicability to many procedures useful in molecular biology, make the method amenable to automation (see column 2, lines 6-12)." So an ordinary practitioner would have been motivated to use the magnetic beads of Hawkins in the place of the beads of Colpan et al (U.S. Patent 5,990,301) or Colpan et al (WO 95/21177) in order to permit rapid throughput, low cost and in order to obtain high yields of the polynucleotides. In particular, Hawkins notes that the beads are amenable to automation.

15. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Colpan et al (U.S. Patent 5,990,301) or Colpan et al (WO 95/21177); in view of Davis et al (U.S. Patent 5,660,984)

Colpan et al (U.S. Patent 5,990,301) or Colpan et al (WO 95/21177) each teach the limitations of claims 1-10, 12 and 33 as discussed above. Neither Colpan et al (U.S. Patent 5,990,301) nor Colpan et al (WO 95/21177) teach the use of a tapered column

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Davis teaches purification of DNA with a tapered column (see abstract and figure 1). Davis teaches a vertical column (see column 7, line 16).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the tapered column of Davis in the method of Colpan et al (U.S. Patent 5,990,301) or Colpan et al (WO 95/21177) since Davis states that the purification column "having a first opening 12 and a second, tapered end having a second opening 13, wherein the first open end has a diameter that is about the diameter of the column and the second opening at the tapered end has a diameter that is less than, preferably substantially less than, the diameter of the column. As is seen in the drawing, the second end preferably has a funnel-shaped taper leading to a columnar opening that can function as an outlet for the column (see column 5, lines 31-37)." An ordinary practitioner would have been motivated to adopt the shape of Davis in the columns of Colpan et al (U.S. Patent 5,990,301) or Colpan et al (WO 95/21177) since Davis indicates that this shape is preferred and since this shape permits a large amount of sample to be concentrated into a smaller area, reducing the amount of DNA lost in the purification procedure.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey Fredman
Primary Examiner
Art Unit 1637
